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Date: September 19, 2005   Lynnea B. Kennelly

Lynnea B. Kennelly

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Johnson et al.	EXAMINER: Peffley
SERIAL NO.: 09/916,214	ART UNIT: 3739
FILED: July 25, 2001	CONFIRMATION NO. 6833
FOR: **APPARATUS FOR DETECTING AND TREATING TUMORS USING LOCALIZED IMPEDANCE MEASUREMENT**	

Appeal Brief Transmittal

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal submitted April 18, 2005, enclosed herewith are the following:

☒ Applicant's Appeal Brief in triplicate.

☒ A Petition for Three-month Extension of Time.

☒ Fees (37 C.F.R. § 1.17(c)): ☒ Large Entity: $ 500.00
(37 C.F.R. § 1.17(a)(3) ☒ Large Entity: $1020.00

- ☒ Enclosed is a check for $1520.00 covering the above fees.
- ☐ Please charge the above fee(s) to Deposit Account No. 50-2207.
- ☒ Please charge any underpayment for timely consideration of this paper to Deposit Account No. 50-2207.

☒ Applicant petitions for an Extension of Time if necessary for timely filing of this Brief.

Respectfully submitted,

Jacqueline F. Mahoney

Date: Sept. 19, 2005

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OIPE IAP78 SEP 19 2005 PATENT & TRADEMARK OFFICE

PATENT

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OIPE IAP78 SEP 19 2005 PATENT & TRADEMARK OFFICE

EXAMINER: Peffley

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APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal to the Board of Appeals and Interferences from the decision of Examiner Peffley mailed November 16, 2004 in which pending claims 38-71 stand in final rejection.

The present paper is Appellants' Appeal Brief submitted in compliance with 37 C.F.R. §1.192.

REAL PARTY IN INTEREST

The real party in interest is RITA Medical Systems, Inc.

RELATED APPEALS, INTERFERENCES, PROCEEDINGS

Appellants are not aware of other appeals, interferences, or judicial proceedings which are related to, would directly affect, be directly affected by, or have a bearing on the Board's decision in the present appeal.

STATUS OF THE CLAIMS

Claims 1-37 stand canceled. Claims 38-71 are pending. In the Office Action Summary mailed November 16, 2004, claims 38-71 are indicated as rejected. However, in the body of the Office Action, rejections are tendered for claims 38-42 and 45-71.

Clarification of the status of claims 43-44 is requested. The final rejection of pending claims 38-71, as presented in Appendix A, is appealed.

STATUS OF AMENDMENTS

Appellant's response submitted subsequent to the Final Office Action contained no amendments to the claims was submitted (Response mailed April 18, 2005). Appellants' response dated April 18, 2005 and submitted after final rejection was entered and made of record.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to an ablation apparatus comprising (i) an elongated delivery device (page 13, lines 19-26, page 15, lines 6-15, and page 27, lines 10-18, element 12 in the figures) including a lumen (page 13, lines 19-24 and 26-27, element 13 in the figures), the elongated delivery device being maneuverable in tissue (page 15, lines 8-10), and (ii) an impedance array (page 16, lines 13-15, element 22a in the figures). The impedance array comprises a plurality of resilient members (page 16, lines 3-6 and page 30, lines 8-16, element 18 in the figures) being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state (page 13, lines 30-31 and page 30 lines 8-16). The resilient members define a sample volume in the deployed state (page 30 lines 12-16). At least two of the plurality of resilient members are a sensor member (page 15, lines 21-26, page 16, lines 3-9, element 22m in the figures) and includes a sensor (page 15, lines 20-25 and page 15, line 26 through page 16, line 2, element 22 in the figures) for determining impedance, where each sensor member is operatively connected to a separate impedance energy source (37, lines 7-11, element 20 in the figures)). At least some of the resilient members are electrodes (page 14, lines 1-4) which can be coupled to at least one ablating energy source (page 30 lines 24-25) for ablating tissue when electrical energy is supplied to the electrodes from the source (page 30 line 24 to page 31, line 9), wherein the impedance array is effective to determine localized impedance (page 9 lines 1-5).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are four grounds of rejection presented for review:

1. The rejection of claims 38-42 and 45-71 35 U.S.C. §102(b) as anticipated by Gough *et al.* (US Patent Application No. 5,683,384; hereinafter "the '384 patent").

2. The rejection of claims 38-42 and 45-71 under 35 U.S.C. §102(b) as anticipated by Gough *et al.* (US Patent Application No. 5,800,484; hereinafter "the '484 patent").

3. The rejection of claims 38-42 and 45-71 under 35 U.S.C. §103(a) as obvious in view of the '384 patent.

4. The rejection of claims 38-42 and 45-71 under 35 U.S.C. §103(a) as obvious in view of the '484 patent.

ARGUMENTS

1.0 Rejection of Claims 38-42 and 45-71 under 35 U.S.C. §102(b) over the '384 patent

According to the M.P.E.P. § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

THE '384 PATENT describes a multiple arm device (Col. 4, lines 18-23) including a primary arm (element 14 in the figures) with a longitudinal axis, and a secondary arm (element 16 in the figures) coupled to the primary arm (Col. 5, lines 34-39). The secondary arm is configured to be deployed in a direction that is lateral to the longitudinal axis of the primary arm (Col. 7, line 66 through Col. 8, line 5) with at least one radius of curvature (Fig. 6A).

The '384 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the presently claimed subject matter. Instead, the '384 patent teaches that energy source can be "an RF source, microwave source, short wave source, laser source and the like" (Col. 6, lines 36-38) and that the apparatus achieves ablation with "RF energy, microwave energy, laser energy, or any

combination thereof (Col. 3, lines 43-45). The '384 patent further teaches the energy source may be a "combination RF/microwave box" (Col. 6, lines 41-42). While the '384 patent describes use of different energy sources, alone or in combination, the patent fails to make any teaching of sensor members each operatively connected to a separate energy source.

In fact, the Office Action states that "there is no explicit disclosure that each electrode/sensor member is connected to a separate energy source" (page 3, Final Office Action mailed November 16, 2004).

However, the Action "maintains that the Gough et al. disclosure inherently suggests the use of different energy sources for each electrode/sensor member" (page 3, Final Office Action mailed November 16, 2004).

The legal standard with respect to inherent anticipation is that "inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may result* from a given set of circumstances is insufficient to prove anticipation." *Contenental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). *In re Oelrich,* 666 F.2d 578, 212 USPQ 323 (CCPA 1981).

Applying this legal standard to the present facts, the claimed feature that <u>each</u> sensor member is operatively connected to a <u>separate</u> impedance energy source must necessarily be present in the disclosure of the '384 patent. Such a disclosure is not necessarily present in the '384 patent. As noted above, the '384 patent teaches a variety of energy sources including RF, microwave, short wave, laser, and a combination RF/microwave box (Col. 6, lines 35-42). The Office Action states that this recitation teaches "that a plurality of energy sources may be connected to individual electrodes/sensors" (page 5, Final Office Action mailed November 16, 2004). Appellants cannot agree. There is nothing in this recitation of energy sources that teaches or even suggests that a separate energy source is connected to each individual electrode. Rather, the recitation is a mere listing of suitable energy sources. Even if the recitation were to be construed as a teaching of multiple energy sources, there are many possible configurations other than each sensor member being

connected to a separate energy source. For example, the recitation of various energy sources could also be construed as either of (i) some of the electrodes being connected to a first energy source and some electrodes being connected to a second energy source, or (ii) all of the electrodes being connected to a combination microwave/RF box as expressly taught. Thus, it does not necessarily follow from this recitation in the '384 patent of a variety of energy sources that each sensor member be operatively connected to a separate impedance energy source.

Although the '384 patent may include electrodes that may be switched between energy sources (i.e. RF and microwave sources), this is certainly not even suggestive of a separate energy source for each sensor member as all of the electrodes may be connected to both sources, or alternatively may be connected to one source, albeit a combination source (Col. 6, lines 41-42).

As there are many possible configurations that could result from the '384 patent teaching of a variety of energy sources, it cannot necessarily follow that each electrode is connected to a separate energy source based on this disclosure.

Accordingly, because the cited '384 patent fails to teach all of the essential elements of the present invention, Appellants urge the Board to overturn the rejection of claims 38-42 and 45-71 based on the '384 patent.

2.0 Rejection of Claims 38-42 and 45-71 under 35 U.S.C. §102(b) over the '484 patent

According to the M.P.E.P. § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

THE '484 PATENT relates to an ablation apparatus (Fig. 1A) comprising an introducer (Col. 1, lines 16-22, element 12 in the figures), two or more electrodes at least partially positioned in the introducer lumen (Col. 1, lines 16-22, element 16 in the figures), wherein each electrode is configured to be advanced from the introducer to define a volumetric ablation volume (Col. 2, lines 36-40 and Col. 3, lines 42-50), and a porous fluid delivery member (Col. 6, lines 21-23 and 33-35, element 23 in the figures)

positioned on at least a portion of an exterior of at least one of the electrodes (Col. 6, lines 26-27).

The '484 patent fails to teach at least two sensor members that includes a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source as in the present invention. The '484 patent makes no mention of a separate energy source for any of the deployable elements. Instead, the '484 patent teaches an electromagnetic energy source connected to the device, which can be a "RF source, microwave source, short wave source, laser source and the like" (Col. 5, lines 1-5). Further, the source may be a "combination RF/microwave box" (Col. 5, lines 7-8). As noted in the Office Action, "there is no explicit disclosure that each electrode/sensor member is connected to a separate energy source (page 3, Final Office Action mailed November 16, 2004). Thus, while the '484 patent describes use of different energy sources, alone or in combination, the patent fails to make any explicit teaching of sensor members each operatively connected to a separate energy source.

Nor does the disclosure of the '484 patent inherently anticipate the claimed method, for all the reasons given above with regard to the '384 patent. Briefly, the claimed feature that each sensor member is operatively connected to a separate impedance energy source is not necessarily be present in the disclosure of the '484 patent as there are many possible configurations that could result from the '484 patent teaching of a variety of energy sources.

Because the cited '484 patent does not teach all of the essential elements of the claimed subject matter, Appellants urge the Board to overturn the rejection of claims 38-42 and 45-71 based on this reference.

3.0 Rejection of Claims 38-42 and 45-71 under 35 U.S.C. §103(a) in view of the '384 patent

According to the M.P.E.P. § 2142, one of the three requirements to establish a case of *prima facie* obviousness, is that the prior art references teach or suggest all the limitations of the claim.

The Office Action states "the use of a separate source for each electrode/sensor member would be an obvious consideration in view of the Gough et al. teaching of using a combination of sources for the electrode/sensor members" (page 3, Final Office Action mailed November 16, 2004).

As noted above, the '384 patent fails to expressly or inherently disclose at least two sensor members that include a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source. Nor would it be obvious to connect each sensor member to a separate energy source. The present invention is particularly concerned with using localized impedance measurement to detect, locate, and identify tumorous tissue as well as monitor a target tissue site and control the course of ablative therapy (page 9, lines 18-23 and page 10, lines 1-6). In another embodiment, the localized impedance measurements may be used to generate an image of a target tissue site and display the image to facilitate the location and monitoring of a tumor and/or ablation volume (page 39, lines 1-4).

Attempts to measure impedance using a full electrical circuit through the patient's body have the drawback of not being able to detect tissue localized impedance. Problems include (i) the signal is too small in relation to and/or masked out by the impedance of the entire impedance measurement system; (ii) the measurement was made too far away on the body from the desired tissue site and is thus masked out; and (iii) the localized impedance was masked out by RF or other ablative energy signal delivered to the tissue (page 9, line 23 through page 10, line 1). These problems are solved in the present apparatus by having at least two sensor members that include a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source.

The '384 patent is not particularly concerned with detecting localized impedance nor the problems associated with detecting localized impedance. The '384 patent teaches measuring voltage with a voltage sensor. Impedance and power are then calculated at power and impedance calculation device (Col. 9, lines 14-16). The impedance measurement is used to define the border or periphery of the ablation zone

(Col. 3, lines 17-21) as well as to permit monitoring and a desired level of ablation to be achieved without destroying too much tissue (Col. 6, line 67 through Col. 7, line 1).

As the '384 patent fails to expressly teach the claimed feature and is not particularly concerned with the problem, the presently claimed feature cannot be said to be an "obvious variation" of the teaching in the '384 patent. Accordingly, Appellants urge the Board to overturn the rejection of claims 38-42 and 45-71 based on this reference.

4.0 Rejection of claims 38-42 and 45-71 under 35 U.S.C. §103(a) in view of the '484 patent

According to the M.P.E.P. § 2142, one of the three requirements to establish a case of *prima facie* obviousness, is that the prior art references teach or suggest all the limitations of the claim.

The Office action states "the use of a separate source for each electrode/sensor member would be an obvious consideration in view of the Gough et al. teaching of using a combination of sources for the electrode/sensor members" (page 4, Final Office Action mailed November 16, 2004).

As noted above, the '484 patent fails to expressly or inherently disclose at least two sensor members that include a sensor for determining impedance, where each sensor member is operatively connected to a separate energy source. Nor would it be obvious to connect each sensor member to a separate energy source. As described above, the present invention is particularly concerned with using localized impedance measurement to detect locate and identify tumorous tissue as well as monitor a target tissue site and control the course of ablative therapy (page 9, lines 18-23 and page 10, lines 1-6). In another embodiment, the localized impedance measurements may be used to generate an image of a target tissue site and display the image to facilitate the location and monitoring of a tumor and/or ablation volume (page 39, lines 1-4).

The '484 patent is not particularly concerned with detecting localized impedance nor the problems associated with detecting localized impedance. Similar to above, the '484 patent teaches measuring voltage with a voltage sensor and calculating

impedance and power with a power and impedance calculation device (Col. 9, lines 12-15). Nowhere does the '484 patent make specific mention of measuring localized impedance.

As the '484 patent fails to expressly teach the claimed feature and is not particularly concerned with the problem, the presently claimed feature cannot be said to be an "obvious variation" of the teaching in the '484 patent. Accordingly, Appellants urge the Board to overturn the rejection of claims 38-42 and 45-71 based on this reference.

CONCLUSIONS

In view of the foregoing remarks, Appellants submit that the pending claims are in condition for allowance and urge the Board to overturn the Examiner's rejections.

Respectfully submitted,

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Date: Sept. 19, 2005

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APPENDIX A: CLAIMS ON APPEAL

38. An apparatus for impedance characterization and ablative treatment of tumors, comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue; and

an impedance array comprising a plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state and defining a sample volume in the deployed state, at least two of the plurality of resilient members being a sensor member and including a sensor for determining impedance, where each sensor member is operatively connected to a separate impedance energy source, at least some of said resilient members being electrodes which can be coupled to at least one ablating energy source for ablating tissue when electrical energy is supplied to the electrodes from the ablating source;

wherein said impedance array is effective to determine localized impedance.

39. The apparatus according to claim 38, wherein said impedance characterization is vector impedance characterization and at least a portion of the impedance array is configured to determine an impedance vector within a selectable tissue site.

40. The apparatus according to claim 38, wherein said impedance characterization is multi-pathway impedance characterization and at least a portion of the impedance array is configured to sample tissue impedance through a plurality of conductive pathways.

41. The apparatus according to claim 40, wherein the plurality of conductive pathways are configured to be substantially evenly distributed or spaced within the sample volume.

42. The apparatus according to claim 38, wherein the plurality of resilient members includes a first, a second and a third resilient member.

43. The apparatus according to claim 38, wherein the sensor has a resistance gradient.

44. The apparatus according to claim 43, wherein the resistance gradient is along a length of the sensor and configured to compensate for resistive losses or hysteresis along the length of the sensor.

45. The apparatus according to claim 38, wherein at least a portion of the impedance array is configured to determine at least one of an intracellular impedance, an interstitial impedance or an intercellular capacitance.

46. The apparatus according to claim 38, wherein the impedance array is configured to determine a locus of impedance within the sample volume.

47. The apparatus according to claim 38, wherein the impedance array is configured to substantially simultaneously determine a first impedance profile at a first tissue site and a second impedance profile at a second tissue site.

48. The apparatus according to claim 47, where, when the impedance characterization is multi-pathway impedance characterization, the first pathway is positioned at a selectable angle relative to the second pathway.

49. The apparatus according to claim 48, wherein the first and second pathway have no common segments.

50. The apparatus according to claim 48, wherein the first and second pathway have a common origin.

51. The apparatus according to claim 50, wherein the first and second pathway have substantially the same pathway, the second pathway being in an opposite direction to the first pathway.

52. The apparatus according to claim 38, wherein the impedance array is configured to detect at least one of an indicator of cell necrosis, a tissue ablation volume, a cell necrosis volume, a tissue thermal volume or a tissue hyperthermic volume.

53. The apparatus according to claim 38, further comprising:

logic resources coupled to at least one of the impedance array or the at least one ablating energy source, and

a processor operatively coupled to the logic resources.

54. The apparatus according to claim 53, wherein at least one of the impedance array or the logic resources is configured to determine or analyze tissue impedance or complex impedance at a frequency distinct from an ablation frequency.

55. The apparatus according to claim 53, wherein the logic resources are configured to identify a tissue condition or differentiate tissue responsive to an impedance signal from the impedance array.

56. The apparatus according to claim 53, wherein the logic resources are configured to analyze an impedance signal at a frequency having an increased tissue condition sensitivity relative to a frequency spectrum.

57. The apparatus according to claim 56, wherein the logic resources are configured to distinguish between normal and abnormal tissue, the abnormal tissue including at least one of abnormally mutated tissue, abnormally dividing tissue, cancerous tissue, metastatic tissue or hypoxic tissue.

58. The apparatus according to claim 53, wherein the logic resources are configured to distinguish between necrosed and non-necrosed tissue.

59. The apparatus according to claim 53, wherein the logic resources are configured to identify one of an inflection point, an asymptote, a minimum or a maximum of an impedance signal.

60. The apparatus according to claim 59, wherein the logic resources are configured to identify at least one of an endpoint, an amount of tissue injury or a tissue type utilizing at least one of the inflection point the asymptote, the minimum or the maximum of the impedance signal.

61. The apparatus according to claim 38, wherein the logic resources are configured to identify an endpoint for an ablation procedure responsive to an impedance signal from the impedance array.

62. The apparatus according to claim 38, wherein the impedance signal includes at least one of an intracellular impedance, an interstitial impedance an intercellular capacitance or a complex impedance, and wherein the logic resources are configured to identify a tissue condition utilizing at least one of an impedance ratio

including at least one of interstitial to intercellular impedance, real to imaginary impedance or impedance to capacitance.

63. The apparatus according to claim 55, wherein the impedance signal is a complex impedance and the logic resources are configured to identify a tissue condition of the sample volume utilizing real and imaginary components of the complex impedance signal.

64. The apparatus according to claim 53, wherein the logic resources are configured to compare the impedance of the first tissue site to an impedance of the second tissue site.

65. The apparatus according to claim 39, wherein the impedance array is configured to detect real and imaginary components of the impedance vector or magnitude and phase angle of the impedance vector.

66. The apparatus according to claim 38, further comprising:

an advancement member coupled to the impedance array, the advancement member including an actuable portion, the advancement member configured to control deployment of at least a portion of the impedance array.

67. The apparatus according to claim 38, wherein at least a portion of the impedance array is configured to sample a complex tissue impedance through a plurality of conductive pathways and detect or measure an indicator of at least one of tumorous tissue or cell necrosis.

68. The apparatus according to claim 38, further comprising:

a multiplexing device operatively coupled to at least some of said plurality of resilient members for multiplexing electrical energy between said plurality of resilient members.

69. The apparatus according to claim 38, wherein the at least one ablating energy source is selected from the group consisting of a RF source, a microwave source, and a laser source.

70. The apparatus according to claim 38, wherein said apparatus operates in a mono-polar mode, said apparatus further comprising:

a ground electrode.

71. The apparatus according to claim 69, wherein said apparatus is switched between a bipolar mode and the mono-polar mode.

APPENDIX B: EVIDENCE

No evidence submitted by Appellant pursuant to 37 C.F. R. §§ 1.130, 1,131, or 1.132 or submitted by the Examiner is relied on in this appeal.

APPENDIX C: RELATED PROCEEDINGS

There are no related proceedings pursuant to 37 C.F.R. § 41.37 (c)(1)(ii).